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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/734,372 | 12/12/2003 | Robert Wood Williams III | 023868.43877 | 2530 |

28172 7590 08/10/2006

BUTLER, SNOW, O'MARA, STEVENS & CANNADA PLLC
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| EXAMINER |
|---|
| STANDLEY, STEVEN H |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/734,372 | WILLIAMS ET AL. | |
| | Examiner | Art Unit | |
| | Steven H. Standley | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *6/05/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 3,15,23-25 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12,14,16-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03&7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group I (claims 1-25), and a method of determining mRNA levels and seq id no 7 as species in the reply filed on 6/05/06 is acknowledged.

In consideration of the species elections, the claims are further limited to 1-12, 14, 16-22, and since claims 13, 15, 23, and 24-25 read upon non-elected subject matter and are withdrawn by the examiner.

### *Specification*

2. The specification should be reviewed for improper recitation of hyperlinks. All such recitations should be deleted or amended such that the hyperlinks are rendered inactive. See MPEP § 608.01.

### *Claim Objections*

3. Claim 21 is objected to because of the following informalities: because it recites MPPX which has no basis in the specification and is very likely a type-o. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-12, 14, and 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of comparing the sensitivity of mouse strains to MPTP treatment by measuring glutathione-s-transferase pi2 mRNA levels in neuronal samples obtained from straitum 8 hours after killing the mice, does not reasonably provide enablement for a method of determining the level of susceptibility to generic "environmental toxins" capable of detoxification by glutathione-s-transferase, or risk of Parkinson's disease by serially sampling a generic 'biological sample' for changes in glutathione-s-transferase mRNA (or anything else in a 'biological sample) ***within*** a subject wherein a second amount being lower than or similar to the first amount indicates the subject is susceptible to a toxin or Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is complex because it claims to measure the level of susceptibility to environmental toxins with unrelated mechanisms of action and unrelated targets of action, and specifically to risk of Parkinson's by measuring glutathione-s-transferase amounts. Thus, the method claims to assess the susceptibility or risk of vastly different things with different etiologies and different targets. The method measures glutathione-s-transferase in samples that are not necessarily affected by the toxin or by Parkinson's disease. The method also claims to measure the full scope of susceptibility to toxins and to Parkinson's by measuring glutathione-s-transferase however changes in expression of glutathione-s-transferase are so complex and change with such varied stimuli that the method has no specificity at all.

The state of the prior (and post-filing date) art is that the levels of glutathione-s-transferase, which is expressed in every cell in the body, decrease not only with environmental toxins, but chronic inescapable stress (see Echjel-Cohen, 2006), meningitis (See Wylie-Modro et al, 1997), diabetes (see Makar et al, 1995), Alzheimer's disease (see Lovell et al, 1998), and mice with a preference for alcohol (Liang et al, 2004). Therefore the method does not work to measure the level of susceptibility to generic "environmental toxins" or to Parkinsons because the method does not distinguish between any of the foregoing. A subject found to meet the criteria in the recited method could have any one of many diseases, disorders or maladies that may or may not be the result from susceptibility to an environmental toxin and may or may not be susceptibility to Parkinsons.

Secondly, the claims recite measuring glutathione-s-transferase (GST) mRNA (as well as protein and enzyme activity) in a generic "biological sample" and in plasma, brain and urine, and the specification teaches measuring GSTP2 in striatal neurons of mice treated with MPTP. It does ***not*** teach measuring mRNA or protein or activity in any other biological sample. The art also indicates GSTs are expressed differentially everywhere in the body (see Pearson et al, 1988, Figure 3, for instance) and therefore measuring changes in mRNA level, or protein, or activity, originating from striatal neurons in the brain from a "biological sample" such as plasma or urine, or even generally in the brain (instead of specifically in the striatum) would be entirely impossible to distinguish from GSTs expressed elsewhere, including GSTP2 which is expressed in the liver as well as brain (and probably elsewhere, see Bammler et al, 1994). Furthermore, the art does not recognize and is silent on measuring mRNA levels originating from striatal neurons in neither another region of the brain nor in any peripheral biological sample such as plasma or urine or even CSF. In other words, mRNA is only measurable in striatal neurons.

Thirdly, the prior art discloses that measuring GST will not determine the level of susceptibility to an environmental toxin or to Parkinson's. For example, a genetically modified mouse (bcl-2) that confers sensitivity to MPTP treatment (see figure 5, Hochman et al, 1998), but does not show significant changes in 'GST activity' (see figure 7, Hochman et al., and see 'antioxidant enzymes,' page 744). Therefore the invention cannot test for "susceptibility" to MPTP which is an environmental toxin by measuring GST levels. Further, polymorphisms in GSTM1 and GSTT1 are not related

to parkinson's as evidenced by Rahbar et al (2000). Therefore the art teaches the invention will not work.

Lastly, the Oligonucleotide of SEQ ID NO: 7 is identical to nucleic acids 1867-1881 of mouse Heparan sulfate proteoglycan 2 (see appendix a), and therefore will not distinguish between GSTP2 of the instant application and the former by in situ hybridization. Therefore, the oligonucleotide claim 14 also will not work.

Because changes in GST levels, including GSTPi2 levels (See Ejchel-Cohen et al) are linked to a plethora of diseases unrelated to environmental toxins, the results of such an assay are unpredictable as to exposure to environmental toxins or susceptibility to such. Also, because GST levels change with a plethora of environmental toxins and diseases, the results are unpredictable as to whether they indicate susceptibility to Parkinson's disease.

The working examples support a link between sensitivity to MPTP toxicity and levels of GSTP2 expressed in striatal neurons of different strains of mice, but the ***specificity*** of the test fails due to the overwhelming number of other things that are linked to increases or decreases in glutathione-s-transferase mRNA, protein, or activity.

The specification supports treating different strains of mice with MPTP, sacking them, and determining the amount of mRNA expressed in striatal neurons, it does not support protein levels, activity levels, or measurements of tissue or fluid samples other than striatal neurons.

Considering the nature of the invention, the contradictory prior art, the unpredictability of the meaning of the results, and the lack of specificity in the teachings of the specification one of skill in the art could not use this invention as claimed.

5. Claims 1-9, 12, 14, and 16-19, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are to a method of determining the level of susceptibility of a subject "***to an environmental toxin*** capable of detoxification by glutathione-s-transferase." The specification, however, teaches only MPTP as an environmental toxin. The claims do not require any structure at all. Therefore, there are no clear structural limitations on the complex of polypeptides claimed. Thus, the claims are drawn to a genus of toxins that are structurally unrelated and unknown. Furthermore, there is no limiting definition of an 'environmental toxin' in the specification.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. In the instant application, no such distinctions have been made. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a functional recitation. Accordingly, in the absence of sufficient recitation of

distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only MPTP and not the full scope of the claim has written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The term "level of susceptibility" in claim 1 is a relative term which renders the claim indefinite. The term "level of susceptibility" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no defined level of susceptibility in the specification. It is a relative term that has no definite meaning.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Odwyer et al (1996).

O'Dwyer et al teach Oltipraz administration of in subjects at risk for colorectal cancer. O'Dwyer et al determine a first amount of GST activity before administration of the environmental toxin (see figure 2, page 1212). O'Dwyer et al then administer Oltipraz which is an environmental toxin (see below). In this case, the patient is "the biological sample that the toxin is contacting. Following administration of otipraz, Odwyer et al measure GST activity (see Figure 2), where the levels go up, which

O'Dwyer et al indicate is protective. Thus the patients then are judged to have a lower susceptibility to colorectal cancer.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kelly et al. (2005) indicate that oltipraz has a level of toxicity to patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
8/7/05

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Appendix A

```
            Clone distribution: MGC clone distribution information can be found
            through the I.M.A.G.E. Consortium/LLNL at: http://image.llnl.gov
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Db       1391 CACCTGGGCCGCTCC 1405


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ACCESSION   BC085618
VERSION     BC085618.1  GI:55715900
KEYWORDS    .
SOURCE      Mus musculus (house mouse)
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            Sciurognathi; Muroidea; Muridae; Murinae; Mus.
REFERENCE   1  (bases 1 to 4315)
  AUTHORS   Strausberg,R.L., Feingold,E.A., Grouse,L.H., Derge,J.G.,
            Klausner,R.D., Collins,F.S., Wagner,L., Shenmen,C.M., Schuler,G.D.,
            Altschul,S.F., Zeeberg,B., Buetow,K.H., Schaefer,C.F., Bhat,N.K.,
            Hopkins,R.F., Jordan,H., Moore,T., Max,S.I., Wang,J., Hsieh,F.,
            Diatchenko,L., Marusina,K., Farmer,A.A., Rubin,G.M., Hong,L.,
            Stapleton,M., Soares,M.B., Bonaldo,M.F., Casavant,T.L.,
            Scheetz,T.E., Brownstein,M.J., Usdin,T.B., Toshiyuki,S.,
            Carninci,P., Prange,C., Raha,S.S., Loquellano,N.A., Peters,G.J.,
            Abramson,R.D., Mullahy,S.J., Bosak,S.A., McEwan,P.J.,
            McKernan,K.J., Malek,J.A., Gunaratne,P.H., Richards,S.,
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            Bouffard,G.G., Blakesley,R.W., Touchman,J.W., Green,E.D.,
            Dickson,M.C., Rodriguez,A.C., Grimwood,J., Schmutz,J., Myers,R.M.,
            Butterfield,Y.S., Krzywinski,M.I., Skalska,U., Smailus,D.E.,
            Schnerch,A., Schein,J.E., Jones,S.J. and Marra,M.A.
  TITLE     Generation and initial analysis of more than 15,000 full-length
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  JOURNAL   Proc. Natl. Acad. Sci. U.S.A. 99 (26), 16899-16903 (2002)
```

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REFERENCE   2  (bases 1 to 4315)
  AUTHORS   Director MGC Project.
  TITLE     Direct Submission
  JOURNAL   Submitted (01-NOV-2004) National Institutes of Health, Mammalian
            Gene Collection (MGC), Cancer Genomics Office, National Cancer
            Institute, 31 Center Drive, Room 11A03, Bethesda, MD 20892-2590,
            USA
  REMARK    NIH-MGC Project URL: http://mgc.nci.nih.gov
COMMENT     Contact: MGC help desk
            Email: cgapbs-r@mail.nih.gov
            Tissue Procurement: Jeffrey E. Green, M.D.
            cDNA Library Preparation: Life Technologies, Inc.
            cDNA Library Arrayed by: The I.M.A.G.E. Consortium (LLNL)
            DNA Sequencing by: Sequencing Group at the Stanford Human Genome
            Center, Stanford University School of Medicine, Stanford, CA  94305
            Web site:       http://www-shgc.stanford.edu
            Contact:  (Dickson, Mark) mcd@paxil.stanford.edu
            Dickson, M., Schmutz, J., Grimwood, J., Rodriquez, A., and Myers,
            R. M.

            Clone distribution: MGC clone distribution information can be found
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ORIGIN

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VERSION     CQ573977.1  GI:41637964
KEYWORDS    .
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            Eukaryota; Metazoa; Arthropoda; Hexapoda; Insecta; Pterygota;
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            Ephydroidea; Drosophilidae; Drosophila.
REFERENCE   1
  AUTHORS   Venter,J.C., Adams,M., Li,P.W. and Myers,E.W.
  TITLE     Detection kits, such as nucleic acid arrays, for detecting the
            expression of 10,000 or more Drosophila genes and uses thereof
  JOURNAL   Patent: WO 0171042-A 1735 27-SEP-2001;
            PE Corporation (NY) (US)
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ORIGIN

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RESULT 16
AE011688/c
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DEFINITION  Xanthomonas axonopodis pv. citri str. 306,  section 66 of 469 of
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ACCESSION   AE011688 AE008923
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